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PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Tick Buster

COMPANY NAME IVC Corporation, Inc.

SUBMISSION PURPOSE Proposed Registration of Use to Control  
Ticks and Fleas

SHAUGHNESSY NO.                      CHEMICAL & FORMULATION                      % AI


## EEB REVIEW

### Permethrin Tick Buster

#### 100.0 Submission Purpose and Label Information

#### 100.1 Submission Purpose and Pesticide Use

The registrant, IVC Corporation, Inc., is requesting a registration of the permethrin product, Tick Buster, to control ticks carried by the white-footed mouse Peromyscus leucopus.

According to the submission, deer ticks are the principal vector responsible for the transmission of the pathogens causing Lyme disease and human babesiosis in the northeastern and central United States. Immature stages of the tick feed mostly on P. leucopus. This mouse species appears to serve as the principal reservoir for both pathogens.

All life stages of the tick are present throughout large tracts of woodland as well as in residential sites. Because the distribution of the tick is well-dispersed, conventional methods of pesticide application such as spraying are impractical in this case. The registrant believes that by treating the mouse's nesting material with permethrin, which is used to control ticks in the home, the ticks which transmit the pathogens can be effectively reduced in numbers to reduce the incidences of these two diseases.

#### 100.2 Formulation Information

Permethrin*	7.4%
Inert Ingredients:	92.6%
	<u>100.0%</u>

\*(3-phenoxyphenyl)methyl(+) cis/trans 3-(2-dichloro-ethenyl)-2,2-dimethyl cyclopropanecarboxylate

cis/trans ratio: Min 35% (+) cis and max 65% (+) trans

Contents: 4.5 g (approximately 30 cottonballs)

#### 100.3 Application Methods, Directions, Rates

Permethrin-impregnated mouse nest material kills ticks and fleas attached to mice and present in the nest.

For the control of disease-transmitting and other ticks and fleas around yards and in woodlots.



## FOR OUTDOOR APPLICATION ONLY

For the control of ticks and other ectoparasites associated with rodents that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and transmit disease to humans, dogs, and horses. The cottonballs enclosed in cardboard dispensing tubes are impregnated with permethrin and are intended as bedding that rodents will remove to their nests. Treatment of nests does not harm rodents but kills disease-transmitting ticks, both on the rodents and in their nests.

To apply, discard plastic endcaps. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 m in any direction. Treatment should be limited to areas inhabited by rodents, and need not include mown lawns or open grasslands. Tubes should be positioned so that rodents have access to the open ends. Product works best if not covered by leaves or other material.

**FOR TREATMENT AROUND YARDS:** Place tubes within 1 m or the edge of mown lawn, in flower gardens, under bushes and along fences, wherever rodents may reside. For complete coverage, all brush-covered or wooded areas within 50 m surrounding the yard area to be protected should be treated. Replace tube when nesting material is completely removed.

**FOR TREATMENT OF WOODLOTS:** Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 m between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Placing tubes near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes should be applied at least twice a year: before April 1 and before August 1. More frequent application, beginning in April and continuing through the summer, will improve results.

**Note:** Do not remove cottonballs from inside of tube. Contact of this material with skin may cause irritation.

### 100.4 Target Organisms

Deer ticks (Ixodes dammini)  
Fleas  
Other ectoparasites



## 100.5 Precautionary Labeling

This product is extremely toxic to fish. Do not apply to areas where contamination of fish-bearing waters is likely. Do not contaminate water by disposal.

## 101.0 Hazard Assessment

### 101.1 Discussion

The permethrin product Tick Buster will be used to control ticks and other ectoparasites on the white-footed mouse Peromyscus leucopus. Cottonballs enclosed in cardboard tubes will be impregnated with permethrin, and the tubes will be placed in wooded areas to be accessible to the mice. The cotton will be carried by the mice to their nests to be used as nesting material. The pesticide in the cotton will kill the disease-transmitting ticks on the mice and in their nests.

Permethrin is fully registered for use on many agricultural crops and around the home and garden for control of many pests including fleas and ticks. The application rates to agricultural crops range from 0.05 to 0.2 lb ai/A.

### 101.2 Likelihood of Adverse Effects to Nontarget Organisms

Permethrin is very highly toxic to aquatic organisms as the LC<sub>50</sub> values for freshwater fish and invertebrates range from 0.32 to 9.8 ppb. However, permethrin is relatively nontoxic to birds and moderately to relatively nontoxic to mammals. The avian LC<sub>50</sub> and LD<sub>50</sub> values for the mallard duck and bobwhite quail are > 10,000 ppm and > 4640 mg/kg, respectively. The mammalian acute oral toxicity values range from 400 to 8000 mg/kg for the rat and from 500 to 700 mg/kg for the mouse. The acute dermal LD<sub>50</sub> value for the mouse is  $\geq$  2500 mg/kg indicating permethrin is relatively nontoxic by this route of exposure.

By enclosing the permethrin-soaked cottonballs in cardboard tubes and placing them at a density of 48 tubes per acre the total active ingredient per acre is only 0.04 lb/A, which is less than the rates already approved for use on a number of agricultural crops. Furthermore, it is very unlikely that the permethrin would enter aquatic systems from this method of application. Therefore, the use of permethrin in Tick Buster will not be unacceptably hazardous to aquatic organisms.

However, Peromyscus will be exposed to the permethrin by carrying the treated cotton to their nests in their mouths and also by nesting in the material and coating



their fur with the chemical. In addition, neonates born in nests containing this material will be more susceptible to dermal contamination since they do not have a protective coat of fur.

Some of the efficacy data that were submitted in EPA Accession No. 265658 indicate that permethrin's toxic activity against ticks persists for 1 to 2 months in the field and up to 6 months over winter. In addition, the fur of mice became impregnated with permethrin which maintained its acaricidal activity for at least 2 days after the mice were removed from the study site. These efficacy testing results indicate that there is a long-term exposure of Peromyscus to permethrin which could be hazardous.

In order to learn if the amount of permethrin to which each mouse could be exposed would be dermally toxic, the amount of permethrin with which each mouse would come into contact was calculated. (The calculations are attached to this review.) In summary, if the percent active ingredient of permethrin in this product is 7.4%, each tube contains 30 cottonballs that weigh a total of 4.5 g, and there are 48 tubes distributed in an acre, the amount of permethrin available per acre is 15.98 g. In a field study (Study 2) submitted by the registrant, mice removed an average of 25% and 30% of the cotton from tubes in grids measuring 0.36 ha over a 3-week period. Each tube contained 10 g of cotton; therefore, 2.5 to 3.0 g of cotton were removed from each tube. If we assume that 3 g is the amount of cotton normally removed from each dispensing tube, then 0.223 g of permethrin will be removed from a tube containing 4.5 g treated with 7.4% permethrin. The amount of permethrin taken by mice per acre is 10.7 g. The density of Peromyscus is 10 to 20 individuals per acre (L. Turner, Pers. Comm.). Therefore, an individual mouse will take 0.54 to 1.07 g permethrin. The acute dermal LD<sub>50</sub> value is  $\geq$  2500 mg/kg body weight. Since a mouse weighs 25 g the LD<sub>50</sub> per mouse is 62.5 mg/mouse, which is considerably less than the amount of permethrin to which each mouse can be exposed (540 to 1070 mg). According to this exposure model, Peromyscus will be exposed to amounts of permethrin that can be hazardous.

There are some flaws with this exposure model. It does not account for the amount of permethrin absorbed through the mouth as the mice carry the cotton to their nests. It assumes that all the cotton removed from the tubes is taken solely by P. leucopus, and all the missing cotton reaches their nests. However, the model still provides a means to look at potential exposure.



Label statements do warn that the product can cause skin irritations. If it can irritate human skin that comes into contact with the treated cotton for a short period of time, what are the effects on small rodents, including neonates, that will nest in it?

In a field study (Study 2) submitted by the registrant, the effects of the treated cotton on mouse populations were assessed. Tubes containing 10 g of permethrin-treated cotton (5%) were placed 10 m apart in 7 x 7 and 5 x 10 grid patterns. Mice were live-trapped in each site at 3-week intervals from May through September 1985. The increase in the number of mice captured in treated and nontreated sites increased 329% and 302%, respectively. A total of 38% of the mice captured in nontreated sites weighed 19 g or less, whereas 47% of the mice captured in treated sites were in that weight class. This difference is not statistically significant.

There appear to be several weaknesses with this study. A sampling interval of 3 weeks is too long; the preferred interval is 1 week or less in order to minimize the influences of immigration and emigration. The method used to estimate population from the rate of capture is not described (e.g., catch effort, mark-recapture). Since the interval between samplings is long, how were the effects of immigration and emigration taken into account? In addition to this information the raw data, including numbers of mice caught per trap per sampling time, age classes of mice caught, lengths of the pre- and postexposure periods and amount of cotton removed from each tube at each sampling period must be given. If the experimental design of the study is flawed, it is very likely this study cannot be used to support the registration of this product. Therefore, we do not have sufficient data to determine the effects on small rodent populations from Tick Buster.

#### 101.3 Endangered Species Considerations

There are no endangered small rodents living in wooded areas around residential areas.

#### 104.4 Adequacy of Toxicity Data

As mentioned in Section 101.2 the field study (Number 2 by Mather et al.) may have significant deficiencies to preclude it from supporting this product. The raw data and explanation of the experimental design and field procedures as described above must be submitted for us to do a full analysis of this study.



Should this study prove to be unacceptable, a laboratory study can be done in lieu of another field study. The basic premise of the laboratory study would be for mice to nest in cotton treated with Tick Buster at the rate specified on the label and observe the mice through one generation so neonates as well as adults are exposed. Since this type of study is not standardized, the registrant is advised to consult with EEB prior to its initiation.

#### 101.5 Adequacy of Labeling

There are several deficiencies with the label.

- X 1) The submission indicates that the disease problems are most prevalent in the northeastern and central United States yet there is no label statement concerning geographic restrictions. If the registrant wants to limit use of this product to these regions of the country the label must clearly name only those States in which it will be used.
- X 2) The distance between tubes is not to exceed 10 m in any direction. No minimum distance is given. If the tubes are to be placed 10 m apart, it should be clearly stated.
- X 3) The tubes are to be applied at least twice a year, but they can be applied more often. A maximum number of applications and the time interval between applications should be stated. The statement "Beginning in April and continuing through the summer" is vague.

#### 103.0 Conclusions

EEB has reviewed the proposed registration of the permethrin product, Tick Buster, for use as a small rodent nesting material in woodlots to control disease transmitting ticks. EEB is unable to complete the risk assessment for this use because pertinent ecological effects data are lacking. In order to assess the risks for this use, EEB requires the following:

- 1) Explanation and full description of the experimental design, field procedures and raw data (as described in Section 101.2) for the field study by Mather et al on the effects of Tick Buster on wild mouse populations.

- 2) If the study is insufficient a laboratory study on the effects of cotton treated with Tick Buster on Peromyscus leucopus through one generation is required. Prior to initiating this study the registrant is advised to consult with EEB.

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### Calculations

$$\frac{7.4\% \text{ permethrin per weight of cotton}}{(0.074)(4.5 \text{ g cotton/tube})} = \underline{0.333 \text{ g permethrin/tube}}$$

$$\frac{48 \text{ tubes/acre}}{0.33 \text{ g permethrin/tube} \times 48 \text{ tubes/A}} = \underline{15.98 \text{ g permethrin/A}}$$

Field Test: 25% to 30% cotton taken from tubes containing 10 g cotton per tube. Therefore, 2.5 to 3 g cotton taken per tube.

Assume 3 g is amount of cotton normally taken from tubes by mice. Then:

$$(3 \text{ g}/4.5 \text{ g})(0.333 \text{ g permethrin/tube}) = \underline{0.223 \text{ g permethrin taken from each tube.}}$$

$$(0.223 \text{ g permethrin/tube})(48 \text{ tubes/A}) = 10.7 \text{ g permethrin taken from each acre.}$$

Assume 10 to 20 mice per acre:

$$\frac{(10.7 \text{ g permethrin/A})}{(10 \text{ to } 20 \text{ mice/A})} = \underline{0.54 \text{ to } 1.07 \text{ g permethrin taken by each mouse}}$$

Acute dermal LD<sub>50</sub> > 2500 mg/kg body weight  
1 mouse weighs 25 g

$$\text{Therefore, } \underline{\text{LD}_{50}/\text{mouse} > 62.5 \text{ mg/mouse}}$$

Attachment



## TICK BUSTER

56783-R, IVC Corp. Boston, MA

Would put <sup>balls</sup> permethrin impregnated cotton in deer mouse's habitat. ~~It~~ Mice would collect this cotton to use as nest material + would control disease vector ticks in the process.

Applicant claims that this "simply represents a new application method" and is not "a new use pattern". This contention is nonsense. It is a new use pattern.

### Application Method

Plastic tubes containing impregnated cotton balls would be placed at intervals of 10 m. or less in deer mouse habitat.

Tubes could be on ground in open in "all brush-covered and wooded areas to be treated." Should not be placed on "mown lawns" but may be placed near lawns, in flower beds, under bushes and along fences, wherever rodents may reside. May also be placed in wood lots, at ~~the~~ intervals  $\leq 10$  m, especially "... near thickets or rotting logs."

Should be placed "at least twice a year: a) before April 1; b) before August 1." — This suggests some ~~permanence~~ persistence.

Cotton balls "may cause skin irritation."

→ Strong possibility that kids will find tubes + "disturb" their contents.

- Should they be dyed? Warnings on tube?

- Might want to use ~~sturdy~~ sturdier, secured <sup>stations</sup> in places near where children might find tubes.



Could probably go Sec. 18 on this thing right away if we had an application. Lyme Disease is nothing to fool around with.

With their Jazzy name (TICK BUSTER), one wonders, however, how much of this interest is in making a buck rather than in disease abatement. The county health dept. should maybe be the agent dispensing this product.

Human safety questions will have to be addressed

Approach is biologically plausible. Data reported are consistent with claims <sup>implied</sup> ~~made~~ for product

( Could say "Aids in the control ~~of~~ <sup>deer</sup> ticks which may carry Lyme Disease )

Bill Jacobs

1/5/87